



Rx: Health Care FYI #22

Subject: *Bad Medicine : Avoiding Counterfeit Drugs*
From: *Rep. Tim Murphy (PA-18)*

The problem: As more and more Americans are unable to afford the rising costs of prescription drugs, price rather than quality has led consumers to purchase over \$32 billion annually in potentially dangerous and/or ineffective counterfeit drugs.¹

Counterfeit drugs are an increasing problem:

- More than 80% of packages intercepted at mail facilities in the United States examined by the Food and Drug Administration (FDA) contained either unapproved foreign drugs, controlled substances or counterfeit drugs.¹
- 10% of all drugs worldwide are counterfeit, and in some countries more than 50% of the drug supply is made up of counterfeit drugs.²
- The United States Postal Service estimates that over 400 million pieces of international mail enter into the United States annually with an average of 12,000 illegal pharmaceutical and controlled substance seizures.³
- The FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990s.³
- Because of sheer volume, many illegal and counterfeit pharmaceuticals still make it through the border and the FDA only has information on 18 percent of the foreign drug manufacturers shipping to the U.S.⁴
- U.S. Customs estimates that 10 million people cross our borders annually carrying illegal and unapproved pharmaceuticals.⁵

Counterfeit drugs increase health risks:

- An individual who receives a counterfeit medication may be at risk for a number of dangerous health consequences such as harmful side effects, allergic reactions, drug-drug interactions, a worsening of their medical condition or death.
- A number of counterfeits do not contain any active ingredients and thus provide no treatment benefit to the patient.
- Counterfeit medications may also contain incorrect ingredients, improper dosages, or hazardous ingredients.
- For example, Procrit, a drug used by cancer and AIDS patients, was replaced with nonsterile tap water, which could have caused a severe infection of the bloodstream. In another example, white tablets with "aspirin" imprinted on them replaced Zyprexa, a drug used for schizophrenia and acute bipolar disorder. This could have been particularly dangerous for patients who are aspirin-sensitive or aspirin-allergic or who have bleeding disorders. In addition, patients no longer received appropriate treatment for their illness.⁶

¹ World Health Organization. Substandard and Counterfeit Medicines. Fact Sheet. November 2003.

² Food and Drug Administration. Counterfeit Drugs Questions and Answers. U.S. Department of Health and Human Services. 2005.

³ Hubbard, William. Associate Commissioner for Policy and Planning, U.S. Food and Drug Administration. U.S. Department of Health and Human Service. July 2004.

⁴ Bliley, Tom. Hearing on Counterfeit Drugs. U.S. House Commerce Committee. June 8, 2000.

⁵ Ahern, Jayson. Testimony. Senate Committee on Governmental Affairs. "Buyer Beware: The Danger of Purchasing Pharmaceuticals over the Internet – Day 2. Federal and Private Sector Responses. July 2004.

⁶ Food and Drug Administration. FDA's Counterfeit Drug Task Force Interim Report. U.S. Department of Health and Human Services. March 2003.

The Federal Government's Role:

- The Prescription Drug Marketing Act (PDMA) (Public Law: 100-293) of 1998 requires drug wholesalers to maintain paper pedigrees or a statement of origin that traces the drug from the point of manufacture and contains information about all transactions that the product undergoes until it reaches the end user. However, the FDA has put off enforcement of this requirement until December 2006 to allow manufacturers to adopt electronic tracking technology.
- In 2004, the FDA issued a final report on Combating Counterfeit Drugs in the United States, available at: <http://www.fda.gov/oc/initiatives/counterfeit/>.
- The U.S. Customs Cybersmuggling Center monitors cybersmuggling activities of illegal drugs. Joint investigations with U.S. and Thai authorities led to the closure of seven on-line pharmacy sites operating in that country, where 245 parcels ready for shipment to the United States contained more than 2.5 million doses of drug products without prescriptions. The drugs included anabolic steroids, Valium, fen-phen and Tylenol with codeine, as well as Xanax (a tranquilizer), and Rohypnol, a powerful sedative sometimes described as the "date rape" drug.

Be a safe consumer:

- Purchase all prescription and over-the-counter medications from U.S. state licensed pharmacies.
- Maintain awareness of your medications. Give your doctor and pharmacist a complete list of all medicines (over-the-counter and prescription) that you use and alert your physician or local pharmacy regarding differences in physical appearance of a product, taste, and side effects.
- For those consumers who purchase medications over the Internet, websites that have the Verified Internet Pharmacy Practice Sites (VIPPS) Seal are licensed pharmacies where FDA-approved medications can be purchased.
- Check to see if a pharmacy is licensed and in good standing. Contact your local state board of pharmacy or the National Association of Boards of Pharmacy (NABP) at <http://www.nabp.net>.
- For those with low incomes, individuals can ask their doctor for samples or referrals to drug manufacturers free or discounted medication programs.
- There are many private and public patient assistance programs that can help eligible patients obtain lifesaving medications at no cost, or at a significant discount without turning to foreign drug sources, including: BenefitsCheckUp (www.benefitscheckup.org/); RxAssist (www.rxassist.org/default.cfm); Needy Meds (www.needy meds.com/); and Partnership for Prescription Assistance (www.helpingpatients.org).

Recommendations:

- Provide adequate resources, including additional tracking technologies, to the FDA and U.S. Customs to protect the American people from counterfeit medications.
- Enforce The Prescription Drug Marketing Act of 1988 today to establish requirements to track drugs from the point of manufacture to the end user to avoid counterfeit medications from invading America's drug supply.
- Increase education of consumers by health care professionals and pharmacies on the dangers of counterfeit drugs and how to protect against these risks.